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Re-evaluation Decision

RVD2010-02

Chlormequat Chloride

(publié aussi en français)

8 March 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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HC Pub: 100093

ISBN: 978-1-100-15021-5 (978-1-100-15022-2)

Catalogue number: H113-28/2010-2E (H113-28/2010-2E-PDF)

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Re-evaluation Decision

After a re-evaluation of the plant growth regulator chlormequat chloride, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing chlormequat chloride for sale and use in Canada.

An evaluation of available scientific information found that products containing chlormequat chloride do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of chlormequat chloride uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of chlormequat chloride was first presented in Proposed Re-evaluation Decision PRVD2009-13, *Chlormequat Chloride*, a consultation document.¹ This Re-evaluation Decision² describes this stage of PMRA's regulatory process for the re-evaluation of chlormequat chloride as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2009-13. To comply with this decision, registrants of products containing chlormequat chloride will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Chlormequat chloride, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of chlormequat chloride. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The USEPA re-evaluated chlormequat chloride and published its conclusions in a 2007 Reregistration Eligibility Decision document.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2009-13, *Chlormequat Chloride*.

What Is Chlormequat Chloride?

Chlormequat chloride is a plant growth regulator used to inhibit plant elongation in ornamentals and winter wheat. Chlormequat chloride is applied by hand wand or groundboom equipment by farm workers and professional applicators.

Health Considerations

Can Approved Uses of Chlormequat Chloride Affect Human Health?

Chlormequat chloride is unlikely to affect your health when used according to the revised label directions.

People could be exposed to chlormequat chloride through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that chlormequat chloride was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per

million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Chlormequat chloride is currently registered in Canada for use on winter wheat and could be used in other countries on crops that are imported into Canada. An MRL for chlormequat chloride is established for wheat at 1.0 ppm. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15,002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Chlormequat Chloride Is Introduced Into the Environment?

Chlormequat chloride is unlikely to affect non-target organisms when used according to the revised label directions.

Terrestrial and aquatic non-target organisms could be exposed to chlormequat chloride in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of chlormequat chloride was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of chlormequat chloride, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- A restricted-entry interval to protect workers re-entering treated sites
- Use restriction limiting number of applications per season

Environment

- Additional advisory label statements to reduce potential surface and groundwater contamination
- Buffer zones to protect non-target, sensitive terrestrial habitats

Appendix I lists all required label amendments.

Other Information

Any person may file a notice of objection³ regarding this decision on chlormequat chloride within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

³ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Chlormequat Chloride

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers, bystanders, and the environment.

- I) The following statements must be included in the **PRECAUTIONS** section:

Do not enter or allow worker entry into treated areas for 12 hours following application.

- II) The following statements must be included in the **DIRECTIONS FOR USE** section:

DO NOT exceed 2 applications per crop cycle for greenhouse ornamentals.

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT apply by air.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

Buffer zones:

The buffer zone specified in the table below is required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of application	Crop	Buffer zones required for the protection of terrestrial habitat (metres)
Field sprayer	Winter wheat	1

If this pest control product is to be used on a commodity that may be exported to the U.S. and you require information on acceptable residue levels in the U.S., visit CropLife Canada's web site at: www.croplife.ca.

III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

Observe buffer zones specified under DIRECTIONS FOR USE.

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (*e.g.* sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between area and the edge of the water.